

AMENDMENTS TO THE CLAIMS

1. **(Currently amended)** An immunogenic composition suitable for administration to a vertebrate host which comprises:

(a) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;

(b) a protein antigen immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and immunogenic protein antigens; and

(c) one adjuvant, which is a mineral-based, negatively charged adjuvant, said composition produced by a method comprising preincubating or subsequently mixing said mineral-based negatively charged adjuvant with said at least one protein antigen immunogenic component prior to formulating with said polynucleotide immunogenic component.

2. **(Previously presented)** The immunogenic composition according to claim 1 wherein said mineral-based negatively charged adjuvant is an aluminum salt or a calcium salt.

3. **(Previously presented)** The immunogenic composition according to claim 2 wherein said aluminum or calcium salt is selected from the group consisting of aluminum phosphate, aluminum hydroxyphosphate, phosphate-treated aluminum hydroxide, calcium phosphate, calcium hydroxyphosphate, and phosphate-treated calcium hydroxide.

4. **(Previously presented)** The immunogenic composition according to claim 1 wherein said group of model protein antigens range from acidic isoelectric point (IEP) proteins to alkaline IEP proteins.

5. **(Previously presented)** The immunogenic composition according to claim 1 wherein said group of immunogenic protein antigens is selected from the group consisting of a surface protein or a core protein of Hepatitis B virus (HBV), a de-toxified toxin from the bacteria *Clostridium tetani* (a tetanus toxoid), a de-toxified toxin from the bacteria *Clostridium botulinus*

(a botulinus toxoid), and a de-toxified toxin from the bacteria *Corynebacterium diphtheriae* (a diphtheria toxoid).

6. **(Previously presented)** The immunogenic composition according to claim 1 wherein said group of immunogenic protein antigens comprises protein antigens derived from inactivated poliovirus.

7. **(Canceled)**

8. **(Previously presented)** A kit comprising an immunogenic composition as defined in claim 1 in a unit dose form for administration to a vertebrate recipient.

9. **(Previously presented)** A method of making the combined immunogenic composition as defined in claim 1, comprising preincubating or subsequently mixing the mineral-based, negatively charged adjuvant with said at least one protein antigen immunogenic component; and adding said polynucleotide immunogenic component to the adjuvant protein mixture to form the combined immunogenic composition.

10. **(Previously presented)** An immunogenic composition suitable for administration to a human host which comprises:

(a) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said human host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;

(b) a protein antigen immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and immunogenic protein antigens; and

(c) a mineral-based, negatively charged adjuvant,
wherein said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein antigen immunogenic component prior to formulating with said polynucleotide immunogenic component.

11. **(Previously presented)** A kit comprising an immunogenic composition as defined in claim 1 in a unit dose form for administration to a human recipient.

Application No.: 10/509,498
Filing Date: October 27, 2004

12. **(Previously presented)** A method for preparing the immunogenic composition according to claim 1, wherein a mineral-based negatively charged adjuvant is preincubated or subsequently mixed with at least one protein antigen immunogenic component prior to formulating with a polynucleotide immunogenic component.